K130626 pg 1 of 5



MAY 1 2013

# 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

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| Date: | March 7, 2013 |
| Submitter: | GE Healthcare<br>(GE Medical Systems Information Technologies, Inc.)<br>8200 West Tower Avenue<br>Milwaukee, WI 53223 |
| Primary Contact Person: | Ms. Carol Ailoian<br>Regulatory Leader<br>GE Healthcare<br>(GE Medical Systems Information Technologies, Inc.)<br>Telephone: 224 280-1008<br>Fax: 847 589 8524 |
| Secondary Contact Person: | Mr. Philip Malca<br>Regulatory Affairs Director<br>GE Healthcare,<br>(GE Medical Systems Information Technologies, Inc.)<br>Telephone: 33(0) 1 3070 4207<br>Fax: 33(0) 1 3070 4399 |
| Device Trade Name: | Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording Systems v6.9.5 |
| Common/Usual Name: | Hemodynamic and Electrophysiology (EP) Recording Systems |
| Classification Names:<br>Product Code: | 21 CFR 870.1425 Computer, Diagnostic Programmable<br>DQK |
| Predicate Device(s): | K111200 Mac-Lab, CardioLab, ComboLab, and SpecialsLab System |

**GE Healthcare**
510(k) Premarket Notification Submission
Mac-Lab, CardioLab, ComboLab, SpecialsLab v 6.9.5

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| Device Description: | Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems are hemodynamic and electrophysiology (EP) recording systems.<br><br>The product will be available in the following configurations: Mac-Lab System, CardioLab System, SpecialsLab System, or a combination of both Mac-Lab and CardioLab marketed as the ComboLab System. The product designated as SpecialsLab is the same as the Mac-Lab System with the exception that it will support fewer options. The SpecialsLab System performs the same intended use as the Mac-Lab, executes the same software, and runs on the same hardware.<br><br>The Mac-Lab, CardioLab, and ComboLab Recording Systems are each available in several configurations ranging from basic to advanced functionality. |
| Intended Use: | **Mac-Lab**<br>The Mac-Lab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The Mac-Lab System is configurable. Clinical data includes: ECG waveforms, heart rate, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, hemodynamic measures [e.g. valve gradients and areas, cardiac output, shunts, Fractional Flow Reserve (FFR), invasive and noninvasive blood pressure] Physiological parameters such as diastolic, systolic, and mean pressures, and heart rate are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.<br><br>Procedural information and optional anatomical and physiological imaging and data devices may be interfaced (e.g. X-ray, ultrasound, patient monitors and information systems). The Mac-Lab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).<br><br>Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.<br><br>The Mac-Lab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The Mac-Lab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.<br><br>The Mac-Lab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical |

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| | facility via network connectivity. The Mac-Lab System also functions as a stand-alone device. The Mac-Lab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. cardiac catheterization and radiology), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.<br>**CardioLab**<br>The CardioLab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The CardioLab System is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and cycle length are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.<br>Procedural information and optional anatomical and physiological imaging and data devices may be interfaced [e.g. X-ray, ultrasound, mapping systems, ablation generators (e.g. RF and cryogenic)], stimulators, patient monitors and information systems. The CardioLab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).<br>Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.<br>Optional accessories for hardware and software includes a waveform simulator to be used exclusively outside active patient care settings. The waveform simulator may be used for training, demonstration without a patient attached, and as a troubleshooting tool on the CardioLab System.<br>The CardioLab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The CardioLab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.<br>The CardioLab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The CardioLab System also functions as a stand-alone device. The CardioLab System is used in a variety of hospital and clinical settings including interventional laboratories |

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| | (e.g. electrophysiology and cardiac catheterization), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.<br>**ComboLab**<br>The ComboLab System is the combination of both the Mac-Lab and CardioLab Systems. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System, although only one system may be used at a time. The ComboLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab and CardioLab Systems.<br>**SpecialsLab**<br>The SpecialsLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab System. Products designated as a SpecialsLab System support fewer options than the Mac-Lab system. |
| Technology: | The proposed Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems employ the same fundamental scientific technology as the predicate devices.<br>The proposed Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording Systems v 6.9.5 adds an additional data acquisition alternative. In addition to TRAM, the Patient Data Module (PDM) is now supported – inclusive of software, service tools, and hardware (PDM and base station).<br>Additionally the proposed v 6.9.5 includes software application enhancements to existing features and functions, including the following:<br>• Receive and store movies and additional snapshots from CARTO™ system<br>• Provide expanded functionality to allow currently available signal data to be requested on-demand<br>• Allow association of user defined author names to entries recorded in the procedure log<br>• Additional window on Mac-Lab to allow a duplicate display of recorded pressure measurements.<br>• Enhanced presentation of the Medication Summary windows<br>• Enhanced existing waveform export to include ablation data export and added additional example algorithm<br>• Enhanced Service Utilities<br>• Support for additional versions of third party software for Antivirus and Backup solutions<br>• Hardware and software updates to address normal technological advancement and obsolescence issues |

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| Determination of Substantial Equivalence: | Summary of Non-Clinical Tests:<br>The Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems and their applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:<br>▪ Risk Analysis<br>▪ Requirements Reviews<br>▪ Design Reviews<br>▪ Testing on unit level (Module verification)<br>▪ Integration testing (System verification)<br>▪ Performance testing (Verification)<br>▪ Safety testing (Verification)<br>▪ Simulated use testing (Validation)<br><br>Summary of Clinical Tests:<br>The subject of this premarket submission, Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems and their applications did not require clinical studies to support substantial equivalence. |
| Conclusion: | GE Healthcare considers the Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems and their applications to be as safe, as effective, and performance is substantially equivalent to the predicate device(s). |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 1, 2013

GE Healthcare
C/O Philip Malca
Regulatory Affairs Director
8200 West Tower Avenue
Milwaukee, Wisconsin 53223

Re: K130626
Trade/Device Name: Mac-Lab, Cardio-Lab, ComboLab, and SpecialsLab Recording Systems
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 29, 2013
Received: April 2, 2013

Dear Mr. Malca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**GE Healthcare**
510(k) Premarket Notification Submission
Mac-Lab, CardioLab, ComboLab, SpecialsLab v 6.9.5

510(k) Number (if known): To be Assigned

Device Name: Mac-Lab, CardioLab, ComboLab, SpecialsLab Recording System(s)

Indications for Use: **Mac-Lab**

The Mac-Lab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The Mac-Lab System is configurable. Clinical data includes: ECG waveforms, heart rate, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, hemodynamic measures [e.g. valve gradients and areas, cardiac output, shunts, Fractional Flow Reserve (FFR), invasive and noninvasive blood pressure] Physiological parameters such as diastolic, systolic, mean pressures, and heart rate are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced (e.g. X-ray, ultrasound, patient monitors and information systems). The Mac-Lab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

The Mac-Lab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The Mac-Lab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The Mac-Lab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The Mac-Lab System also functions as a stand-alone device. The Mac-Lab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. cardiac catheterization and radiology), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

Prescription Use_x____ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number (if known): To Be Assigned

Device Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems

Indications for Use:

**SpecialsLab**
The SpecialsLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab System. Products designated as a SpecialsLab System support fewer options than the Mac-Lab system.

**ComboLab**
The ComboLab System is the combination of both the Mac-Lab and CardioLab Systems. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System, although only one system may be used at a time. The ComboLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab and CardioLab Systems.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**GE Healthcare**
510(k) Premarket Notification Submission
Mac-Lab, CardioLab, ComboLab, SpecialsLab v 6.9.5

510(k) Number (if known): To Be Assigned

Device Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording System(s)

Indications for Use: **CardioLab**

The CardioLab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The CardioLab System is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and cycle length are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

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Prescription Use_X____ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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